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TOWNSEND and TOWNSEND and CREW LLP

By: Lisa McDill

PATENT
Attorney Docket No. 018158-024500US
Client Ref. No. VX-1209

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERANCES

In re application of:

CHERNYAK, DIMITRI A. et al.

Application No.: 10/808,728

Filed: March 24, 2004

For: CALIBRATING LASER BEAM POSITION AND SHAPE USING AN IMAGE CAPTURE DEVICE

Confirmation No. 5629

Examiner: David Shay

Technology Center/Art Unit: 3735

APPELLANTS' BRIEF UNDER 37 CFR §41.37

Mail Stop Appeal Brief
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Further to the Notice of Appeal mailed on June 30, 2008 for the above-referenced application, Appellants submit this Brief on Appeal.

Appendix A, attached hereto, contains a copy of all claims pending in this case. Appendix B, attached hereto, is marked as the evidence appendix. Appendix C, attached hereto, is marked as the related proceedings appendix.

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1. REAL PARTY IN INTEREST

All right, title and interest in the subject invention and application are assigned to AMO Manufacturing USA, LLC, having offices at 1700 E. St. Andrew Place, Santa Ana, CA 92705-4933. Therefore, AMO Manufacturing USA, LLC is the real party in interest.

2. RELATED APPEALS AND INTERFERENCES

No other appeals or interferences are known which will directly affect, or be directly affected by, or have a bearing on the Board's decision in the pending appeal.

3. STATUS OF CLAIMS

Claims 1-32 were originally presented in the subject application. In the Amendment filed on December 14, 2007, claims 1, 15, 16, 17, 18, 23 and 24 were amended.

The amendments have been entered. Claims 1-32 are pending. As indicated by the Final Office Action of March 28, 2008, all pending claims stand rejected.

4. STATUS OF AMENDMENTS

An Amendment was filed on December 14, 2007 and has been entered. A Final Office Action was mailed on March 28, 2008. A Notice of Appeal was filed on June 30, 2008. A copy of all the pending claims involved in the appeal is provided in the attached Appendix A.

5. SUMMARY OF CLAIMED SUBJECT MATTER

The appealed claims are directed toward methods and systems for calibrating laser pulses from a laser system. These systems and methods generally take advantage of microscope structures that have long been included with laser surgical systems. However, rather than merely visually monitoring the eye surface during an ongoing surgery, the microscope can instead help calibrate the laser system before the surgery, typically through the use of an optical image processing system and a simple calibration target that is temporarily positioned at the eye treatment plane. More specifically, an exemplary laser eye surgery system (10) generally has an image capture device (20) oriented for imaging an eye during laser eye surgery. [Fig. 1, para. 31

of the subject application (hereinafter "subject application")]. A pulsed laser beam (26) of the laser eye surgery system (10) is directed onto a calibration surface so as to leave a mark (28) on the calibration surface (18), such as by using a calibration surface that is discolored by the laser, that fluoresces in response to the laser, or the like. [*Id.* at paras. 31 and 32] The image capture device (20) images the mark (28) and also images a known object (30), with the known object often comprising a simple high-contrast circle disposed at the treatment plane. [*Id.*, see also Figs. 2 and 9A] The imaged mark and object each have an imaged size, shape and location. [*Id.* at paras. 13, 14, and 35] A laser beam cross-sectional shape, location and/or size of the laser eye surgery system can be calibrated by comparing the image of the mark (28) to that of the known object (30). [*Id.* at paras. 9, 46, 47]

The image-based laser eye surgery calibration techniques of the present invention can, for example, help quantify a subtle (and apparently, previously unrecognized) source of laser surgical error: variable aperture hysteresis. Specifically, the use of the image of the known object (30) allows the magnification of the image capture device (20) to be quantified, generally by applying a fitting routine to the optical image data of the mark (28) and the known object (30) so as to accurately and precisely measure and calibrate the laser beam cross-sectional size. [*Id.* at paras. 9, 35, 46] By comparing the imaged object size with the imaged mark size, a relationship between laser beam diameter and motor counts associated with a variable aperture (116) of the laser eye surgery system can be determined. Further, the diameter setting of the pulsed laser beam (26) can be increased over time and then decreased over time, forming a plurality of marks. These marks are imaged, and any hysteresis (such as variability in measured sizes of the aperture related to prior aperture sizes) can be determined and accounted for. [*Id.* at Figs. 8A, 8B, paras. 9, 41, 42, and 47] Although small, because the amount of hysteresis can be significant to the desired precision associated with corrections to the optics of a patient's eye, separate calibration data for an increasing aperture and a decreasing aperture may enhance the accuracy of laser ablations. [*Id.*]

As recited in independent claim 1, a method for calibrating laser pulses from a laser eye surgery system (10) is disclosed. The laser eye surgery system (10) has an image capture device (20) oriented for imaging an eye during laser eye surgery. [*Id.* at Fig. 1, para. 31].

A known object (30) is imaged with the image capture device (20). [*Id.*, see also Figs. 2 and 9A] The imaged object has an imaged object size, an imaged object shape, and an imaged object location. [*Id.* at paras. 13, 14, and 35] A pulsed laser beam (26) of the laser eye surgery system (10) is directed onto a calibration surface so as to leave a mark (28) on the calibration surface (18). [*Id.* at paras. 31 and 32] The image capture device (20) images the mark (28) with the image capture device (20). The imaged mark has an imaged mark size, imaged mark shape, and imaged mark location. [*Id.* at paras. 13, 14, and 35] A laser beam cross-sectional shape, location and/or size of the laser eye surgery system is calibrated by comparing the image of the mark (28) on the calibration surface to the image of the known object (30). [*Id.* at paras. 9, 46, 47]

As recited in independent claim 15, a method for calibrating laser pulses from a laser eye surgery system (10) using an image capture device (20) is also disclosed. A known objection (30) is imaged with the image capture device (20). A pulsed laser beam (26) is directed onto a calibration surface (18) so as to leave a mark (28) on the calibration surface. [*Id.* at Fig. 1, paras. 31 and 32] The diameter setting of the pulsed laser beam (26) is increased over time with a variable aperture (116) so as to form a plurality of marks (28), which are imaged and compared with the known object (30). The diameter setting of the pulsed laser beam (26) can then be decreased over time with the variable aperture (116). The laser eye surgery system (10) is calibrated by comparing the image of the mark on the calibration surface to the image of the known object (30). The calibration of the laser eye surgery system comprises determining a hysteresis of the variable aperture (116).

As recited in independent claim 23, a method for calibrating laser pulses from a laser eye surgery system (10) having a microscope camera (20) is also disclosed. A known object (30) is imaged with the microscope camera (20) oriented toward an eye treatment plane of the laser eye surgery system. The imaged known object (30) has a known object size. A pulsed laser beam (26) is scanned across a photosensitive material disposed along the eye treatment plane so as to leave an ablation on the photosensitive material. The ablation on the photosensitive material is imaged with the microscope camera (20), while the photosensitive material is disposed along the eye treatment plane. The imaged ablation has an ablation size. [*Id.* at Figs. 1 and 2, paras. 31, 32, 38, and 39] An iris calibration of the laser eye surgery system

is determined by comparing the ablation size in the image of the ablation on the photosensitive material to the known object size in the image of the known object. [*Id.* at paras. 40, 41, 46, and 47] A patient's cornea is ablated with the calibrated system (10). [*Id.* at paras. 34 and 37]

As recited in independent claim 24, a system for calibrating laser pulses (26) from a laser system (10) is also disclosed. The system comprises an image capture device (20), a known object (30), a pulsed laser beam delivery system (10), a calibration surface (18), and a processor (22). [*Id.* at Fig. 1, para. 31] The image capture device (20) is oriented toward a treatment plane. The known object (30) is positionable for imaging by the image capture device (20). The pulsed laser beam delivery system (10) is oriented for directing a pulsed laser beam (26) toward the treatment plane. The calibration surface (18) is supportable in an optical path (32) of the pulsed laser beam (26) so as to result in a mark (28) on the calibration surface and for imaging of the mark (28) on the calibration surface by the image capture device (20). The processor (22) is coupled to the image capture device (20) and determines a calibration of the laser beam delivery system (10) by comparing the image of the mark (28) on the calibration surface (18) to the image of the known object (30). [*Id.* at paras. 31 and 32]

As can be understood with the above summary and with reference to the subject application, for example, from paragraphs 6 and 9 of the subject application, the claimed systems and methods provide a relatively simple, low cost, and yet highly accurate and precise means of calibrating laser beam cross-sectional size, shape, and/or location. Moreover, these techniques can be applied through a novel use of an existing piece of equipment--a microscope--that is already included in a wide variety of laser eye surgery systems, but which has not previously been employed to provide such laser calibration data.

6. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. Whether or not claim 1-32 has been shown to be unpatentable under 35 U.S.C. §103(a) over U.S. Patent No. 6,116,737 issued to Kern (hereinafter "Kern") in combination with U.S. Patent No. 4,732,148 issued to L'Esperance, Jr. (hereinafter "L'Esperance").

B. Whether or not claim 15 has been shown to be unpatentable under §103(a) over Kern in view of L'Esperance.

7. ARGUMENT

A. Rejection of claims 1-14, and 16-32 under 35 U.S.C. §103(a):

In the Final Office Action of March 28, 2008, claims 1-32 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Kern in combination with L'Esperance. For the reasons below, Appellant respectfully traverses these rejections.

Claims 1-32 were rejected as being obvious over the combination of Kerr and L'Esperance. Claims 2-14, and 16-22 depend from independent claim 1. Claims 25-32 depend from independent claim 24. Independent claims 1, 23 and 24 share many related limitations. A known object is imaged with an image capture device or a microscope, a pulsed laser beam is directed onto or scanned over a calibration surface so as to leave a mark or ablation, the mark or ablation is imaged with the image capture device, and the laser beam is calibrated by comparing the imaged known object with the imaged mark or ablation. Advantageously, individual (or small groups of) laser pulses of different size, location, and/or shape may be compared to the known object and used for efficient correction of specific aspects (variable aperture, scanning optics, etc.) of these sophisticated laser eye surgery systems which are out of calibration without having to resort to separate and expensive measurement devices.

Under 35 U.S.C. §103(a), a patent may not be obtained if the difference between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art. [M.P.E.P. §2141] The Supreme Court in Graham v. John Deere Co., 383 U.S. 1, 17, 148 USPQ 459, 467 (1966), clarified that a rejection under §103 requires that the scope and contents of the prior art be determined, the differences between the prior art and the claims at issue be ascertained, and that the level of ordinary skill in the art be resolved. Secondary considerations such as commercial success, long-felt but unresolved need, failure of others, etc. must also be evaluated.

First addressing the scope and contents of the prior art, Kern relates to the creation of an ablative profile, which is measured and compared with an intended ablative profile so as to allow for adjustment of an ablative laser's parameters (col. 1, ln. 12-22; col. 2, ln. 66 - col. 3, ln. 18). In the Kern approach, a specially formulated collagen material having an ablation rate approximately equal to that of corneal tissue is ablated (col. 2, ln. 32-38). The surface profile or shape of the ablation is measured with a surface profiling instrument, preferably a non-contact interferometer (see Kern: col. 3, ln. 43-54; col. 4, ln. 29-42). The Kern methodology then seeks to confirm or adjust the operating parameters of the laser system based on the surface shape profile measurements (see Kern: col. 3, ln. 51-53). Thus, Kern indicates that the laser system is to be calibrated by first forming an ablation profile or shape in an artifical cornea, and if a surface shape measurment indicates any overall inaccuracies, by then seeking to identify the source of the error. As it can take hundreds or even thousands of individual pulses to form the Kern ablation profile, there is no indication how the Kern technique could be used, for example, to measure individual pulse locations that are slightly off-set so as to allow correction of a scan motor non-linearity.

L'Esperance relates to devices and techniques for surgically operating upon the outer surface of the cornea (see L'Esperance: col. 1, ln. 62-64). An apparatus effectively fixes the position of an eye with respect to a what appears to be a non-scanning laser, and a sculpturing action upon the outer surface of the cornea results from the controlled change of the projected laser spot size over the course of a treatment (see L'Esperance: col. 2, ln. 13-28). The laser spot size is changed through the use of a zoom lens, an indexible mask, or an indexible mirror (see L'Esperance: col. 2, ln. 28-35). While the L'Esperance reference may disclose a significant and historic advancement in the field, the reference simply does not appear to identify any calibration techniques that could, for example, identify, measure, and correct scan motor non-linearities.

Moving on to address the differences between the prior art and the claims at issue, Appellants note that numerous elements of claims 1-32 are not disclosed by either Kern, L'Esperance, or any reasonable combination of both. Neither cited reference discloses the currently claimed imaging of a known object with a microscope or image capture device. As can

be understood from the above, this use of a known object greatly contributes to the precision with which the microscope can optically identify a location, size, and/or shape of an individual beam pulse(or small group of pulses) at the eye treatment plane. Also, neither cited reference discloses comparing the image of the known object with the image of a mark on a calibration surface to calibrate the shape, location and/or size of a laser beam. Although Kern may disclose the goal of calibrating a laser system, the Kern calibration is based on interferometer measurement of the depth profiles of ablation made on a sample material. Hence, no image from a microscope oriented toward an eye-treatment plane is used whatsoever in the Kern calibration, much less are such images compared with images of a known object taken by the same microscope. Moreover, measurement of an ablated surface shape by even a specialized and expensive interferometer would not as readily or directly provide the cross-sectional shape, location and size of the laser beam. In contrast, size, shape, and/or location of a scanned beam pulse are directly available using the methods of claims 1-23 and systems of claims 24-32. L'Espereance does not disclose the calibration of any laser system, much less the imaging of a known object and comparing that imaged object with an imaged laser pulse mark using a treatment monitoring microscope. Therefore, Kern and L'Esperance, alone or in combination, fail to disclose each and every element of the claims at issue. For at least this reason, the claims at issue are allowable over Kern and L'Esperance.

In a standard Graham analysis, the level of ordinary skill in the art must also be resolved and secondary considerations must also be considered. The inventions claimed in the subject application include methods and systems pertaining to calibrating laser pulses particularly from laser eye surgery systems. Thus, persons of ordinary skill in the art would likely be able to understand the primary concepts disclosed in the Kern and L'Esperance references, and might well be familiar with devices (and their related methods of use) that were widely in use in the field at the time the subject application was filed. Hence, such a skilled artisan might understand both the advantages and disadvantages of non-contact interferometers as described in Kern and the laser eye surgery devices described by L'Esperance, as such devices and methods significantly pre-date the time the claimed invention was made (L'Esperance having issued in 1988 and Kern in 2000, while the subject application was filed in 2004). Yet, the

relatively simple, cost effective, and highly advantageous methods and systems now claimed (including calibrating laser beam size, shape, and/or location by comparing an image of a laser beam mark and an image of a known object, where both images are obtained using an eye-monitoring microscope) has ***not*** been shown prior to the present invention. In fact, based on the cited references, the trend in the field and in the related industry appear to be away from the use of such a straightforward method. Kern, for example, teaches the use of separate and more complex surface profiling instruments such as a non-contact interferometer. Thus, the present invention solves the long felt but unsolved need for providing a simple and straightforward method of precisely and accurately calibrating laser beam size, shape, and/or location.

For the reasons set forth above, claims 1-32 are allowable over the combination of Kern and L'Esperance. Appellants respectfully request withdrawal of the rejections to the claims at issue.

B. Rejection of claim 15 under 35 U.S.C. §103(a):

Independent claim 15 also has many limitations similar to those of independent claims 1, 23 and 24, as described above. Thus, for at least the reasons discussed above with reference to claims 1-14, and 16-32, claim 15 is allowable over the combination of Kern and L'Esperance.

Claim 15 further recites increasing and decreasing the pulsed laser beam diameter setting with a variable aperture and that the calibrating of the laser eye surgery system comprises determining a hysteresis of the variable aperture. Although Kern discloses a method for calibrating an ablation, increasing and decreasing the diameter of the laser beam with a variable aperture is not remotely disclosed. Kern also does not even remotely disclose determining a hysteresis of a variable aperture. L'Esperance does not disclose a calibration method but does discloses the use of a variable aperture and indexible masks or mirrors. Yet, L'Esperance also fails to disclose determining a hysteresis of the variable aperture, much less even appreciates that hysteresis may be present in the variable aperture and indexible masks or mirrors.

Appellants also note that the use of variable apertures is well known to those of ordinary skill in the art well before the claimed invention was made. L'Esperance discloses the use of a variable aperture and was issued in 1988. Yet, determining a hysteresis of the variable

aperture by comparing the image of a mark to the image of a know object does not appear to have been recognized as having any relevance to laser eye surgery until the present invention. In fact, the presence and potential impact of hysteresis in a variable aperture laser eye surgery system does not appear to have ever been appreciated until the present invention. As shown in Figs. 8C and 8D and described in paragraphs 0013, 0041 and 0042 of the subject application's specification, such hysteresis and any associated non-linearity may be very small and may even remain completely hidden if one was not specifically looking for them. However, the present application recognizes that such hysteresis and non-linearity present in laser eye surgery system can (and ideally should) be accounted for so that they do not impose a slight (but potentially significant) error in ablation shapes imposed on test articles and eyes of patients.

For the reasons set forth above, claim 15 is allowable over the combination of Kern and L'Esperance. Appellants respectfully request withdrawal of its rejection.

8. CONCLUSION

For these reasons, it is respectfully submitted that the rejections set forth in the Final Office Action mailed on March 28, 2008 should be reversed.

Respectfully submitted,

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9. CLAIMS APPENDIX

1. (Previously Presented) A method for calibrating laser pulses from a laser eye surgery system, the laser eye surgery system having an image capture device oriented for imaging an eye during laser eye surgery of the eye, the method comprising:

imaging a known object with the image capture device of the laser eye surgery system, the imaged object having an imaged object size, an imaged object shape, and an imaged object location;

directing a pulsed laser beam of the laser eye surgery system onto a calibration surface so as to leave a mark on the calibration surface;

imaging the mark on the calibration surface with the image capture device of the laser eye surgery system, the imaged mark having an imaged mark size, an imaged mark shape, and an imaged mark location; and

calibrating a laser beam cross-sectional shape, a laser beam cross-sectional location, and/or a laser beam cross-sectional size of the laser eye surgery system by comparing the image of the mark on the calibration surface to the image of the known object.

2. (Original) The method of claim 1, wherein the imaged object comprises a circular shape having a known diameter.

3. (Original) The method of claim 2, wherein the known object comprises a circular chrome layer on a glass plate.

4. (Original) The method of claim 1, further comprising removing the known object prior to directing the pulsed laser beam onto the calibration surface.

5. (Original) The method of claim 1, wherein the imaging of the known object and of the mark on the calibration surface is carried out in the same position.

6. (Original) The method of claim 1, wherein the directing and imaging are carried out in the same plane.

7. (Original) The method of claim 1, wherein the directing and imaging are carried out in at least one of a laser focus plane or a treatment plane, and wherein imaging of the

known object and imaging of the mark on the calibration surface are performed along an imaging optical path coaxial with a laser optical path.

8. (Original) The method of claim 1, wherein the calibration surface comprises photosensitive material, silkscreen material, Zapit paper, luminescent material, or photographic material.

9. (Original) The method of claim 8, wherein the mark on the calibration surface comprises a permanent change in color or a luminescent glow.

10. (Original) The method of claim 1, wherein the calibration surface comprises photoreactive material or polymethylmethacrylate material.

11. (Original) The method of claim 10, wherein the mark on the calibration surface comprises an ablation.

12. (Original) The method of claim 1, wherein the mark on the calibration surface has a diameter setting in a range from about 0.65 mm to about 6.7 mm.

13. (Original) The method of claim 1, further comprising increasing the pulsed laser beam diameter setting over time so as to form a plurality of marks, imaging the marks, and comparing the marks to the known object.

14. (Original) The method of claim 13, further comprising decreasing the pulsed laser beam diameter setting over time.

15. (Previously Presented) A method for calibrating laser pulses from a laser eye surgery system using an image capture device, the method comprising:

imaging a known object with an image capture device;

directing a pulsed laser beam onto a calibration surface so as to leave a mark on the calibration surface;

imaging the mark on the calibration surface with the image capture device;

increasing the pulsed laser beam diameter setting over time with a variable aperture so as to form a plurality of marks, imaging the marks, and comparing the marks to the known object;

decreasing the pulsed laser beam diameter setting over time with the variable aperture; and

calibrating the laser eye surgery system by comparing the image of the mark on the calibration surface to the image of the known object, the calibrating of the laser eye surgery system comprising determining a hysteresis of the variable aperture.

16. (Previously Presented) The method of claim 1, further comprising determining a relationship between laser beam diameter and motor counts associated with an iris setting of the laser eye surgery system by comparing the imaged object size with the imaged mark size.

17. (Previously Presented) The method of claim 1, further comprising determining a shape of the laser beam by comparing the imaged object shape with the imaged mark shape.

18. (Previously Presented) The method of claim 1, further comprising determining a center position of the laser beam by comparing the imaged object location with the imaged mark location.

19. (Original) The method of claim 1, further comprising determining a drift of the laser eye surgery system by monitoring a variance in center positions for each scanned and imaged laser pulse.

20. (Original) The method of claim 1, further comprising determining a laser beam deflection.

21. (Original) The method of the claim 1, further comprising rotating an optical element along a laser delivery path and identifying a rotation-induced laser induced wobble from a plurality of marks.

22. (Original) The method of claim 1, further comprising ablating a patient's cornea with the calibrated system.

23. (Previously Presented) A method for calibrating laser pulses from a laser eye surgery system having a microscope camera, the method comprising:

imaging a known object with the microscope camera oriented toward an eye treatment plane of the laser eye surgery system, the imaged known object having a known object size;

scanning a pulsed laser beam across a photosensitive material disposed along the eye treatment plane so as leave an ablation on the photosensitive material;

imaging the ablation on the photosensitive material with the microscope camera while the photosensitive material is disposed along the eye treatment plane, the imaged ablation having an ablation size;

determining an iris calibration of the laser eye surgery system by comparing the ablation size in the image of the ablation on the photosensitive material to the known object size in the image of the known object; and

ablating a patient's cornea with the calibrated system.

24. (Previously Presented) A system for calibrating laser pulses from a laser system comprising:

an image capture device orientated toward a treatment plane;

a known object positionable for imaging by the image capture device;

a pulsed laser beam delivery system oriented for directing a pulsed laser beam toward the treatment plane;

a calibration surface supportable in an optical path of the pulsed laser beam so as to result in a mark on the calibration surface and for imaging of the mark on the calibration surface by the image capture device; and

a processor coupled to the image capture device, the processor determining a calibration of the laser beam delivery system by comparing the image of the mark on the calibration surface to the image of the known object.

25. (Original) The system of claim 24, wherein the image capture device comprises a microscope camera.

26. (Original) The system of claim 24, wherein the known object comprises a circular chrome layer of known diameter on a glass plate.

27. (Original) The system of claim 24, wherein the known object and calibration surface are imaged in the same position.

28. (Original) The system of claim 24, wherein the known object and calibration surface are positioned in at least one of a laser focus plane or the treatment plane.

29. (Original) The system of claim 24, wherein the laser beam delivery system comprises a laser eye surgery system.

30. (Original) The system of claim 24, wherein the calibration surface comprises photosensitive material, silkscreen material, Zapit paper, luminescent material, photoreactive material, polymethylmethacrylate material, or photographic material.

31. (Original) The system of claim 30, wherein the mark on the calibration surface comprises an ablation, a permanent change in color, or a luminescent glow.

32. (Original) The system of claim 24, wherein the mark on the calibration surface has an iris setting in a range from about 0.65 mm to about 6.7 mm.

10. EVIDENCE APPENDIX

None

11. RELATED PROCEEDINGS APPENDIX

None